

## **REMARKS/ARGUMENTS**

### **Claim Amendments**

By the present amendment, previous claims 100-102 have been renumbered as claims 99-101 to correct a typographical error. This in accordance with the Examiner's comments on page 2 of the current Office Action.

The Applicants submit that no new matter has been added to the claims as a result of these amendments and their entry is respectfully requested.

The Official Action dated July 12, 2007 has been carefully considered. It is believed that the claims submitted herewith and the following comments represent a complete response to the Examiner's rejections and place the present application in condition for allowance. Reconsideration is respectfully requested.

### **35 U.S.C. §103(a)**

The Examiner has rejected claims 1-6, 8-10, 37-38 and 40-48 as obvious over Nakanishi688 (US 5,009,688) in view of Gill (J. Am. Chem. Soc., (1998), 120, 8587-8598) and claims 1-6, 8-10, 37-38, 40-48 and 54-56 as obvious over Nakanishi875 (US 5,624,875) in view of Gill.

The Examiner has maintained the above rejections because the Examiner contends that Exhibit D (Figure 5 and Table 1) filed on April 27, 2007 shows that the sample derived from the PGS-PEO system at pH 10 is bimodal meso/macroporous making the argument filed in the Declaration of John Brennan under 37 CFR §1.132 filed on April 27, 2007 not persuasive.

The Applicants submit that there were errors in the data provided in Table 1 of the Declaration of John Brennan under 37 CFR §1.132 filed on April 27, 2007 and that these errors led the Examiner to believe that the sample derived from the PGS-PEO system at pH 10 had a greater macoporosity than in actuality possessed. When

calculating the total macropore and mesopore volumes and percentages, for previous Table 1, a radius of 50 nm was used instead of a diameter of 100 nm. A corrected table has been submitted herewith in a further declaration of John Brennan under 37 CFR §1.132. As stated in the declaration, the Applicants submit that the small amount of macropores that is shown in Table 1 for the PGS sample is a consequence of cracking during drying, rather than the presence of real macropores. This is supported by the TEM pictures, also re-included in the declaration for the Examiner's reference, where the lack of macropores in the sample derived from PGS is visually apparent.

Further, the Applicants submit that the data in the remaining Figures provided in Exhibit D of the Declaration of John Brennan under 37 CFR §1.132 filed on April 27, 2007 unambiguously support the contention that the sample derived from PGS did not contain macropores. In particular, and contrary to the Examiner's conclusion, the Applicants note that Figure 5, also included in the attached declaration for the Examiner's reference, clearly shows that the DGS sample (sample 1) exhibits macropores (i.e. pores with a diameter between 0.1 and 10  $\mu\text{m}$ ) where the PGS sample (sample 2) does not.

Accordingly, the Applicants submit that the present corrected data, along with the data provided on October 17, 2006 and April 27, 2007, clearly and unequivocally show the unexpected superior results obtained with the preparation of siliceous materials from organic polyol silanes in the presence of water soluble polymers under the conditions claimed herein, in particular compared to the same conditions with the precursors of the cited art. Accordingly, the Applicants submit that the claims submitted herewith are not obvious over the cited art.

In light of the above, the Applicants request that the Examiner's rejection of claims 1-6, 8-10, 37-38, 40-48 and 54-56 under 35 U.S.C. §103(a) be withdrawn.

**35 U.S.C. §102(e)**

The Examiner has rejected claims 1-5, 8-10, 37-38, 40-48 and 54-56 under 35 U.S.C. §102(e) as being anticipated by Brook (US 2004/0034203).

The Applicants have submitted herewith a declaration under 37 C.F.R. §1.131 of the inventors of the present application to demonstrate that the claimed invention was conceived and reduced to practice before the filing of US 2004/0034203 in the United States (i.e. prior to May 31, 2002). Accordingly, the rejection in light of US 2004/0034203 is rendered moot and should be withdrawn.

In light of the above, the Applicant request that the Examiner's rejection of claims 1-5, 8-10, 37-38 and 40-56 under 35 U.S.C. §102(b) or, in the alternative under 35 U.S.C. §103(a), be withdrawn.

The Applicants acknowledge and appreciate the Examiner's indication that claims 7, 11-14 and 57-101 would be allowable if rewritten to overcome the double patenting objection, the claim rejection under 35 U.S.C. §112, first paragraph and/or claim objections set forth in the Office Action, and to include all of the limitations of the base claim and any intervening claims.

The Applicants acknowledge and appreciate the Examiner's indication that claims 39, 57-95 and 97 are allowed.

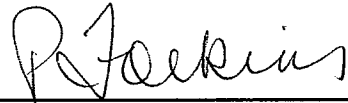
In view of the foregoing arguments and amendments, we respectfully submit that the application is in order for allowance and early indication of that effect is respectfully requested. Should the Examiner deem it beneficial to discuss the application in greater

Appl. No. 10/814,123  
Amdt. dated November 12, 2007  
Reply to Office Action of July 12, 2007

detail, the Examiner is invited to contact the undersigned by telephone at (416) 957-1683 at the Examiner's convenience.

Respectfully submitted,

**BERESKIN & PARR**

A handwritten signature in cursive script, appearing to read "P. Folkins", written over a horizontal line.

By: Patricia Folkins  
Reg. No. 51,379  
Tel: (416) 957-1683

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appl. No : 10/814,123 Confirmation No. : 8039  
Applicant : Zhang, et al.  
Filed : April 1, 2004  
Title : Protein Compatible Methods and Compounds for Controlling the  
Morphology and Shrinkage of Silica Derived from Polyol-Modified  
Silanes  
TC./A.U. : 1712  
Examiner : Kuo Liang Peng  
Docket No. : 3244-126 (Formerly 571-932)

**DECLARATION UNDER 37 C.F.R. 1.131**

Honorable Commissioner for Patents  
P. O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

I, Kerstin Smith, Research Contracts Manager, Office of Research Contracts and Intellectual Property, McMaster University, Hamilton, Ontario, Canada, declare that the following facts are within my knowledge and are true.

1. I am authorized to sign on behalf of McMaster University, the named Assignee of the above-referenced patent application (hereinafter "the application").
2. I have reviewed the Official Action for the application that issued on July 12, 2007.
3. In particular, I note the Examiner's rejection of claims 1-5, 8-10, 37-38, 40-48 and 54-56 under 35 USC §102(e) in view of Brook (US 2004/0034203).
4. Claims 1-5, 8-10, 37-38, 40-48 and 54-56 of the application include a method of preparing bimodal meso/macroporous siliceous materials comprising combining an organic polyol silane precursor with one or more additives under conditions suitable for

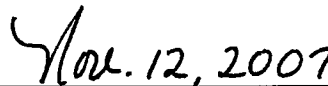
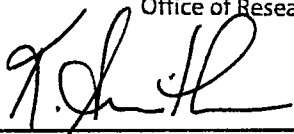
hydrolysis and condensation of the precursor to a siliceous material and for phase separation to occur before gelation, wherein the one or more additives are one or more water-soluble polymers and wherein the conditions comprise combining the organic polyol silane precursor with the one or more additives at a pH in the range of about 4 to 10. We confirm that the invention described in claims 1-5, 8-10, 37-38, 40-48 and 54-56 of the application was made in a NAFTA country (Canada) prior to the filing of US 2004/0034203 in the United States (May 31, 2002).

5. In order to demonstrate that the claimed invention was made prior to May 31, 2002, we refer the Examiner to paragraphs [0088] to [0094] and Example 13, in particular samples D-8 and D-9, of US 2004/0034203. These paragraphs and experiments are also present in the priority document for US 2004/0034203 (i.e. U.S. provisional patent application no. 60/384,084) filed on May 31, 2002.

6. The above experimental results confirm that the invention of claims 1-5, 8-10, 37-38, 40-48 and 54-56 was completed in a NAFTA country (Canada) before the filing of US 2004/0034203 in the United States.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and, further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such a willful false statement may jeopardize the validity of the application or any patent issuing thereon.

Kerstin Smith, Contracts Manager  
Office of Research Contracts & Intellectual Property



DATE

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appl. No	:	10/814,123	Confirmation No.	:	8039
Applicant	:	Zhang, et al.			
Filed	:	April 1, 2004			
Title	:	Protein Compatible Methods and Compounds for Controlling the Morphology and Shrinkage of Silica Derived from Polyol- Modified Silanes			
TC./A.U.	:	1712			
Examiner	:	Kuo Liang Peng			
Docket No.	:	3244-126 (Formerly 571-932)			

Honorable Commissioner for Patents  
P. O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

**DECLARATION UNDER 37 CFR §1.132**

I, John D. Brennan, a citizen of Canada, and resident of Dundas, Ontario, Canada, declare that the following facts are within my knowledge and are true.

1. I reside at 203 Pleasant Avenue, Dundas, Ontario, Canada L9H 3V5.
2. I currently am an Associate Professor in the Department of Chemistry, McMaster University, 1280 Main St. W., Hamilton, Ontario, Canada, L8S 4M1. I also currently hold a Canada Research Chair in Bioanalytical Chemistry.
3. I have been working in the area of bioanalytical chemistry since 1988. My curriculum vitae was attached to the Declaration under 37 CFR §1.132 filed on April 27, 2007 as Exhibit B.

4. I am an inventor, along with Zheng Zhang, Yang Chen, Jorge Cruz-Aguado, Richard J. Hodgson, Dina Tleugabulova and Michael A. Brook, of the subject matter as claimed in U.S. Patent Application No. 10/814,123 filed April 4, 2004 (hereafter "the Application").

5. I have read and understood the disclosure and claims of the Application.

6. I have read and understood the Office Action that issued on the Application on July 12, 2007. The Examiner is of the view that claims 1-6, 8-10, 37-38 and 40-48 are obvious over Nakanishi688 (US 5,009,688) in view of Gill (J. Am. Chem. Soc., (1998), 120, 8587-8598) and claims 1-6, 8-10, 37-38, 40-48 and 54-56 are obvious over Nakanishi875 (US 5,624,875) in view of Gill. It is my understanding that the Examiner has maintained these objections because the Examiner contends that Exhibit D (Figure 5 and Table 1) filed on April 27, 2007 shows that the sample derived from the PGS-PEO system is bimodal meso/macroporous making the argument filed in my Declaration under 37 CFR §1.132 filed on April 27, 2007 not persuasive.

7. I have reviewed the data provided in Table 1 in my Declaration under 37 CFR §1.132 filed on April 27, 2007 and note that there were errors in the data provided in Table 1 that may have led the Examiner to believe that the sample derived from the PGS-PEO system had a greater macroporosity than it actually possessed. When calculating the total macropore and mesopore volumes and percentages, for previous Table 1, a radius of 50 nm was used instead of a diameter of 100 nm. A corrected table has been submitted herewith as Exhibit A. The small amount of macropores that is shown in Table 1 for the PGS sample is a consequence of cracking during drying, rather than the presence of real macropores. This is supported by the TEM pictures (also re-included in Exhibit A for the Examiner's reference) where the lack of macropores in the sample derived from PGS is visually apparent. With respect to Figure 5, which shows the pore size distribution for DGS-PEO (Sample 1) and PGS-PEO (sample 2)



prepared at pH 10 (also re-included in Exhibit A for the Examiner's reference) I submit that the data presented in this graph clearly indicate that the PGS sample prepared at pH 10 did not have any macropores (i.e. pores with a diameter between 0.1  $\mu\text{m}$  and 10  $\mu\text{m}$ ). I submit that the data in Table 1 and Figures 1 and 5 prove that the DGS sample (sample 1) exhibits macroporosity and mesoporosity, where the PGS sample (sample 2) does not.

8. The experimental results in Exhibit A confirms the unexpected results obtained when DGS (a polyol modified silane) is used as the precursor in the preparation of siliceous materials at pH 10, the upper limit of the pH range claimed in the present application. The unexpected results at the lower limit of the pH range were shown in the declaration of Michael A. Brook filed with the Applicants Response dated October 17, 2006.

9. Further, the experimental results in Exhibit A, combined with those provided in my Declaration filed on April 27, 2007, and in the declaration of Michael A. Brook filed with the Applicants Response dated October 17, 2006, show that DGS, used in the methods claimed by the present Applicants, is fundamentally different from the material(s) prepared in Gill, Nakanishi688 and Nakanishi875. Specifically, in the presence of PEO (10K MW), DGS was the only precursor that provided macro/mesoporous material within the pH range claimed in the present application.

10. In summary, I believe that Applicants are entitled to claim a method of preparing bimodal siliceous material by combining polyol-modified silanes with one or more water soluble polymers under conditions where a phase separation occurs before gelation. I am of the opinion that the claims pending in Application are not obvious in view of Gill in combination with Nakanishi688 or Nakanish875, since the substitution of DGS for the alkoxysilanes used in both of the Nakanishi patents would not be expected to provide the bimodal macro/mesoporous siliceous material that is obtained using the method of the present invention.

This is substantiated by the fact that experiments performed in our own labs have demonstrated that PGS, when combined with a water soluble polymer in the method as claimed in the Applicants' application does **not** provide bimodal meso/macroporous siliceous material.

11. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statement and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the Application or patent resulting therefrom.

Nov 12 / 07  
Date

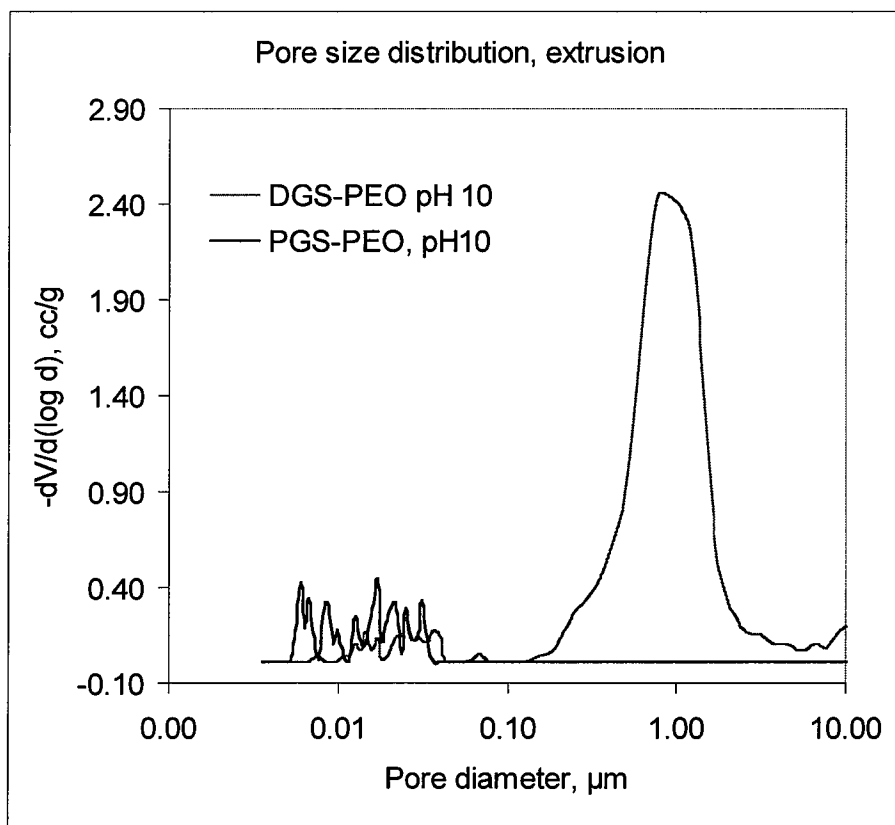
  
John A. Brennan

## EXHIBIT A

**Table 1. Mercury Porosimetry intrusion Data Summary for DGS-PEO (Sample 1) and PGS-PEO (sample 2) prepared at pH 10.**

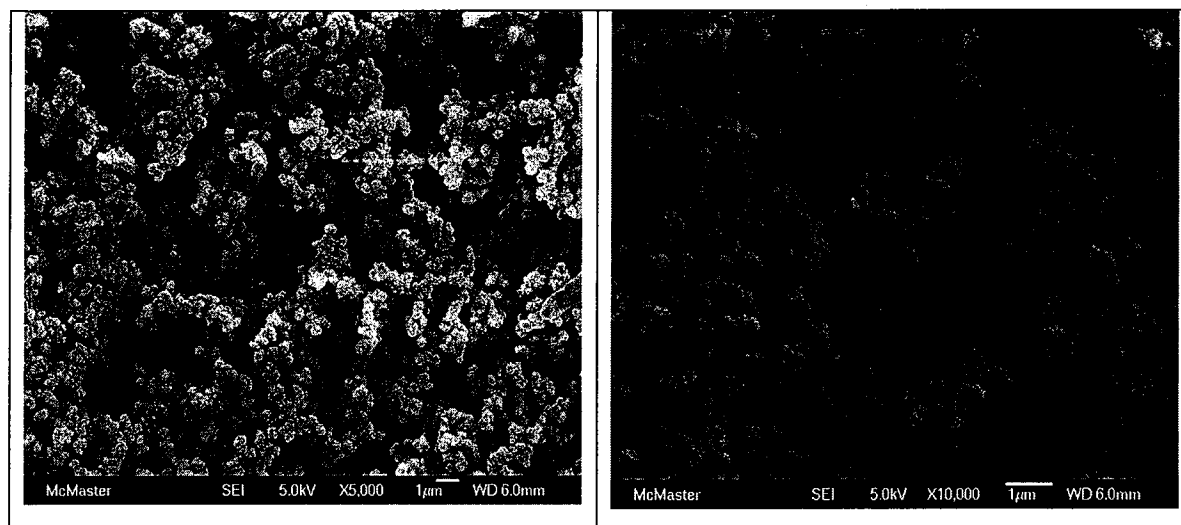
	DGS-PEO	PGS-PEO
Total Surface Area, m <sup>2</sup> /g	269.1610	366.2633
Total Intruded Volume, cc/g	3.6647	1.3828
Total Macropore Volume, cc/g	3.3172	0.2242
Total Mesopore Volume, cc/g	0.3475	1.1586
Percentage of Macropore Volume	90.52 % (>100 nm)	16.21 % (>100 nm)
Percentage of Mesopore Volume	9.48 % (<100 nm)	83.79 % (<100 nm)
Macropore size (median), μm	0.51 and 4.07	<0.1 (very broad pore size distribution)
Mesopore size(median), μm	0.0048	0.023

**Figure 5. Pore size distribution for DGS-PEO (Sample 1) and PGS-PEO (sample 2) prepared at pH 10**



**Figure 1: SEM images of DGS-derived (Sample 1) and PGS-derived (Sample 2).**

Sample 1 (*DGS/pH 10/8% PEO10K*) (different magnification)



Sample 2 (*PGS/pH 10/8% PEO10K*) (different magnification)

